160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Common Formats for Patient Safety Data Collection

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health

and Human Services (HHS).

ACTION: Notice of Availability – New Common Formats

SUMMARY: As authorized by the Secretary of HHS, AHRQ coordinates the development

of common definitions and reporting formats (Common Formats) for reporting on health

care quality and patient safety. The purpose of this notice is to announce the availability of

Common Formats for Event Reporting – Diagnostic Safety (CFER-DS) Version 1.0.

DATES: Ongoing public input.

ADDRESSES: The *Common Formats for Event Reporting - Diagnostic Safety (CFER-DS)*

Version 1.0 can be accessed electronically at the following website:

https://www.psoppc.org/psoppc_web/publicpages/commonFormatsOverview.

FOR FURTHER INFORMATION CONTACT: Dr. Hamid Jalal, Center for Quality

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SUPPLEMENTARY INFORMATION:

Background on Common Formats Development

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), 42 U.S.C.

299b-21 to b-26, and the related Patient Safety and Quality Improvement Final Rule (Patient

Safety Rule), 42 CFR Part 3, published in the Federal Register on November 21, 2008, 73

FR 70731-70814, provide for the formation of Patient Safety Organizations (PSOs), which

collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The collection of patient safety work product allows for the aggregation of data that help to identify and address underlying causal factors of patient safety and quality issues.

The Patient Safety Act provides for AHRQ to develop standardized reporting formats using common language and definitions (Common Formats) for reporting on health care quality and patient safety that will ensure that data collected by PSOs and other entities have comparable clinical meaning. The Common Formats facilitate aggregation of comparable data at local, PSO, regional and national levels.

Since February 2005, AHRQ has convened the Federal Patient Safety Work Group (PSWG) to assist AHRQ in developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS as well as the Departments of Defense and Veterans Affairs. The PSWG helps assure the consistency of definitions/formats with those of relevant government agencies. In addition, AHRQ has solicited comments from the private and public sectors, since 2008, regarding proposed versions of the Common Formats through a contract with the National Quality Forum (NQF), which is a non-profit organization focused on health care quality. After receiving comments, the NQF solicits review of the formats by its Common Formats Expert Panel. Subsequently, NQF provides this input to AHRQ who then uses it to refine the Common Formats before issuing a production version.

AHRQ previously developed and maintains Common Formats for three settings of care — acute care hospitals, skilled nursing facilities, and community pharmacies — for use by healthcare providers and PSOs. AHRQ-listed PSOs are required to collect patient safety

work product in a standardized manner to the extent practical and appropriate, a requirement the PSO can meet by collecting such information using Common Formats. Additionally, health care providers and other organizations not working with an AHRQ-listed PSO can use the Common Formats in their work to improve quality and safety; however, they cannot benefit from the Federal confidentiality and privilege protections of the Patient Safety Act.

The CFER-DS is the first AHRQ Common Formats for Event Reporting that can be used across healthcare settings. It is designed to capture standardized, structured data to facilitate the reporting of diagnostic safety events for the purpose of learning about how to improve diagnostic safety and better support the diagnostic process.

The CFER-DS is not designed for frontline incident reporting. It is intended to facilitate the collection and organization of a basic set of meaningful data about diagnostic safety events that can be used, aggregated and analyzed for learning and improvement. Having a common frame of reference and standardized data elements makes shared learning possible at local, regional, and national levels. Users decide if and how to integrate collection of specific CFER data elements into their incident reporting systems and other existing work processes.

At this time, AHRQ is releasing the CFER-DS Version 1.0 Event Description and some supporting materials, including the Users' Guide and Form. A Sample Preliminary Clinician Event Report is also being made available as a convenience for optional use or adaptation as a supporting resource to the CFER-DS. Additional supporting documents and technical specifications for the CFER-DS (e.g., Data Dictionary, Flow Charts, Resources Workbook) are anticipated to be released in Fall 2022.

Information on how to comment on Common Formats is available at:

http://www.qualityforum.org/Project_Pages/Common_Formats_for_Patient_Safety_Data.as
px.

Additional information about the AHRQ Common Formats can be obtained through

AHRQ's PSO website: https://pso.ahrq.gov/common-formats.

Dated: June 3, 2022.

Marquita Cullom,

Associate Director.

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